CLINICAL RESEARCH STUDIES

From the Western Vascular Society

Early outcome of "cutting" balloon angioplasty for infrainguinal vein graft stenosis

Karthikeshwar Kasirajan, MD,[a] and **Peter A. Schneider, MD,**[b] *Atlanta, Ga; and Honolulu, Hawaii*

Background: **Recurrent stenotic lesions associated with vein graft bypass grafts are often fibrous and smooth. Unlike de novo atherosclerotic lesions, they respond poorly to balloon angioplasty, and may often result in a dissection requiring stent placement to avoid early recurrent thrombosis or open repair of residual stenosis. A novel balloon designed with three or four longitudinally placed 0.127-mm atherotomes was used at angioplasty to treat focal peripheral vein graft stenosis, in an attempt to minimize dissection by producing a controlled plaque fracture.**

Methods: **Over 11 months, patients with focal (<2 cm) peripheral vein graft stenosis underwent cutting balloon angioplasty (Boston Scientific, San Diego, Calif) at two separate centers. Baseline patient demographic data, type of bypass, velocity at pre-procedural and post-procedural duplex scanning, procedural results, complications, and type of long-term anticoagulation were recorded. Follow-up consisted of duplex ultrasound scanning at 1, 3, and 6 months and every 6 months for 2 years.**

Results: **The mean age of the patients was 66.8 ± 10 years. No intent to treat failure was noted. In most patients a 4-mm balloon was used (15 of 19) to treat 10 above-knee vein bypass grafts and 9 below-knee vein bypass grafts. No patient required placement of a stent or conversion to open surgery because of recoil, dissection, or suboptimal angioplasty. The mean velocity at pre-procedure duplex scanning at the site of vein graft stenosis was 373 ± 56.8 cm/s, and the mean velocity post-treatment at 1-month follow-up was 144 ± 50 cm/s. The mean length of stay was 26 ± 32 hours. Overall, four patients continued to receive warfarin anticoagulation therapy, in addition to aspirin. During a mean follow-up of 11.4 ± 7 months, recurrent stenosis developed in one patient. No other complications or graft recurrent thrombosis was noted.**

Conclusion: **Cutting balloon angioplasty may help overcome hoop stress early, by producing a controlled, longitudinal neointimal lesion laceration and thereby facilitating a fracture line along predetermined microincisions. Our study results demonstrate acceptable early outcomes, with no requirement for bail-out stenting or open surgery. (J Vasc Surg 2004; 39:702-8.)**

Vein bypass grafts are currently considered the most durable and effective for limb salvage in patients with limb-threatening lower extremity ischemia.[1,2] However, vein bypass grafts may develop stenotic lesions and thrombosis over time. Surveillance programs improve the long-term graft patency and limb salvage by as much as 10% to 15%, and revision of stenosis identified at duplex scanning is significantly less expensive and more successful than revision after graft thrombosis.[3] Since the initial serial angiographic surveillance by Szilagyi et al,[4] it has been adequately demonstrated that intrinsic vein graft stenosis is the most likely culprit for occlusion 30 days to 5 years after vein graft implantation. The vast majority of these graft-threatening lesions are focal, and their prompt correction returns the patency curve to that of a graft in which stenosis has never developed.[5] However, if graft thrombectomy or lysis was required before identification of the culprit stenosis, the 1-year patency rate was a dismal 20% to 35%.[6-8]

Numerous studies have demonstrated the efficacy and durability of open surgical repair in the treatment of infrainguinal vein bypass graft stenosis.[6,9] However, open surgical correction of these lesions is not always straightforward, and may require complex reconstructive techniques to maintain graft patency and limb salvage. The use of percutaneous methods of treating vein graft stenosis has resulted in varying outcomes, and the role of percutaneous angioplasty (PTA) to treat focal vein graft stenosis has not yet been defined. We report the use of a novel balloon for the treatment of focal vein graft stenosis.

From Department of Surgery,[a] Emory University School of Medicine, Atlanta, and Division of Vascular Therapy,[b] Hawaii Permanente Medical Group, Honolulu.

Competition of interest: none.

Presented at the Eighteenth Annual Meeting of the Western Vascular Society, Kohala Coast, Hawaii, Sep 20-23, 2003.

Reprint requests: Karthikeshwar Kasirajan, MD, Department of Surgery, Emory University Hospital, Rm H-122A, 1364 Clifton Rd NE, Atlanta, GA 30322 (e-mail: karthik_kasirajan@emoryhealthcare.org).

0741-5214/$30.00

doi:10.1016/j.jvs.2003.10.046

METHODS

Data were prospectively entered into a computer data base, and supplemented with chart reviews when required. Patients with a vein bypass graft stenosis, as defined with duplex criteria,[10] were offered diagnostic angiography and possible PTA. Cutting balloon PTA was restricted to lesions less than 2 cm long and vein grafts with a duplex scan diameter of at least 3 mm in the segment with stenosis. Data collected included patient demographics, type of vein bypass, indications for bypass, status of inflow and outflow vessels, time to stenosis after the initial bypass procedure, pre-procedure and post- procedure anticoagulation therapy, velocity at pre-procedure and post-procedure duplex scanning, maximum balloon diameter, complications, and recurrent stenosis or thrombosis of the treated conduit.

Device description. The cutting balloon has currently been approved for angioplasty of coronary de novo resistant lesions. Hence it is designed with coronary specifications. The balloon has 3 to 4 atherotomes, with a height equivalent to that of a coronary strut (0.005 inches [0.127 mm]). The length of the atherotome is 15 mm, and the length of the balloon is 18 mm (Fig 1). The base of the atherotome has T notches, to increase flexibility during balloon passage. The metal atherotome is bonded to a mounting pad, and the mounting pad plus atherotome is then "glued" to the surface of the balloon and is exposed only during balloon inflation. The balloon is made of a noncompliant polyethylene therephthalate material with a nominal pressure of 6 atm and a rated burst pressure of 10 atm. The balloon is available in diameters ranging from 2 to 4 mm, with a crossing profile of 0.041 to 0.046 inches (1.04-1.16 mm). The catheter is a monorail system, with the distal part enabling rapid exchange over a standard 0.014-inch guide wire.

Technique of balloon angioplasty. Access was routinely obtained through a contralateral femoral puncture. An initial aortoiliac angiogram was obtained to exclude an inflow lesion. Selective cannulation of the contralateral common femoral artery was then performed, followed by placement of a 6F up-and-over sheath (Pinnacle Destination; Boston Scientific, Maple Grove, Minn). The vein bypass graft and outflow vessels were imaged before angioplasty of the vein graft stenosis. All patients were given 5000 IU of intravenous heparin during the intervention, and had been taking oral aspirin for a minimum of 1 week before the procedure. Once the culprit lesion was identified, it was crossed with a 0.014-inch guide wire, followed by a cutting balloon of adequate diameter. Only lesions less than 2 cm long were treated with this technique. The balloon was inflated slowly, enabling the balloon and atherotome to open completely. The balloon was then deflated and reinflated at least once more. A completion angiogram of the treatment zone and the outflow vessels was obtained.

Surveillance after cutting balloon angioplasty. An initial duplex scan is obtained at the first clinic visit (<1 month) after PTA. Subsequent clinic visits and studies were planned for 3 months and then every 6 months for 2 years.

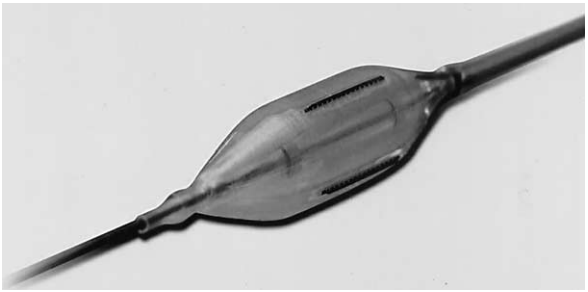

Fig 1. Cutting balloon with longitudinally molded atherotomes.

Annual studies are to be obtained for the lifetime of the patient or graft. A peak systolic velocity (PSV) greater than 300 cm/s or a PSV that is three and one-half times that of an adjacent normal segment would be considered highly indicative of a vein graft stenosis. If progressive increase in the PSV is noted in the treatment zone, but not reaching the revision threshold, the studies would be repeated every 2 months until the lesion resolves or progresses to the point of requiring revision.

RESULTS

Overall, 19 consecutive patients with focal vein graft stenosis received treatment over 11 months. Three additional patients with diffuse vein graft stenosis underwent surgical revision (patch in 1 patient, replacement vein graft in 2 patients) during the same study period. Although this was not a prospective study, all focal vein graft stenosis seen by the two physicians over the 11 months were successfully treated with the cutting balloon; hence there was no intent-to-treat failure. All treated conduits were vein bypass grafts. Overall, 10 bypass grafts were in the above-knee location, and 9 were to a below-knee target vessel (4 below-knee popliteal, 5 tibial or peroneal). All above-knee bypass grafts were reversed, and 2 of the below-knee bypass grafts were in situ saphenous vein grafts. Four of the above-knee bypass graft procedures were performed to treat claudication, and the others were for limb salvage. The average time to stenosis in the above-knee bypass grafts was 17.4 ± 18.2 months (range, 3-63 months), and in the below-knee bypass grafts was 12.5 ± 16.4 months (range, 1-54 months). Sites of stenosis included the proximal anastamosis in 9 patients, mid-graft in 7 patients, and distal location in 3 others. The maximum balloon diameter used was 4 mm in 15 grafts, and a 3-mm or 3.5–mm balloon was used in the other 4 grafts. We were able to achieve an angiographic stenosis of less than 10% in all patients after cutting balloon PTA. No local or systemic complications were noted. All patients were given aspirin therapy before and after the procedure, and 4 patients continued to receive warfarin anticoagulation therapy for other systemic reasons. The mean duration of hospital stay was 26 ± 32 hours. All but 1 patient not receiving warfarin was sent home the same day. The mean velocity at pre-procedure and post-procedure duplex scanning is presented in the Table I, along with patient demographic data.

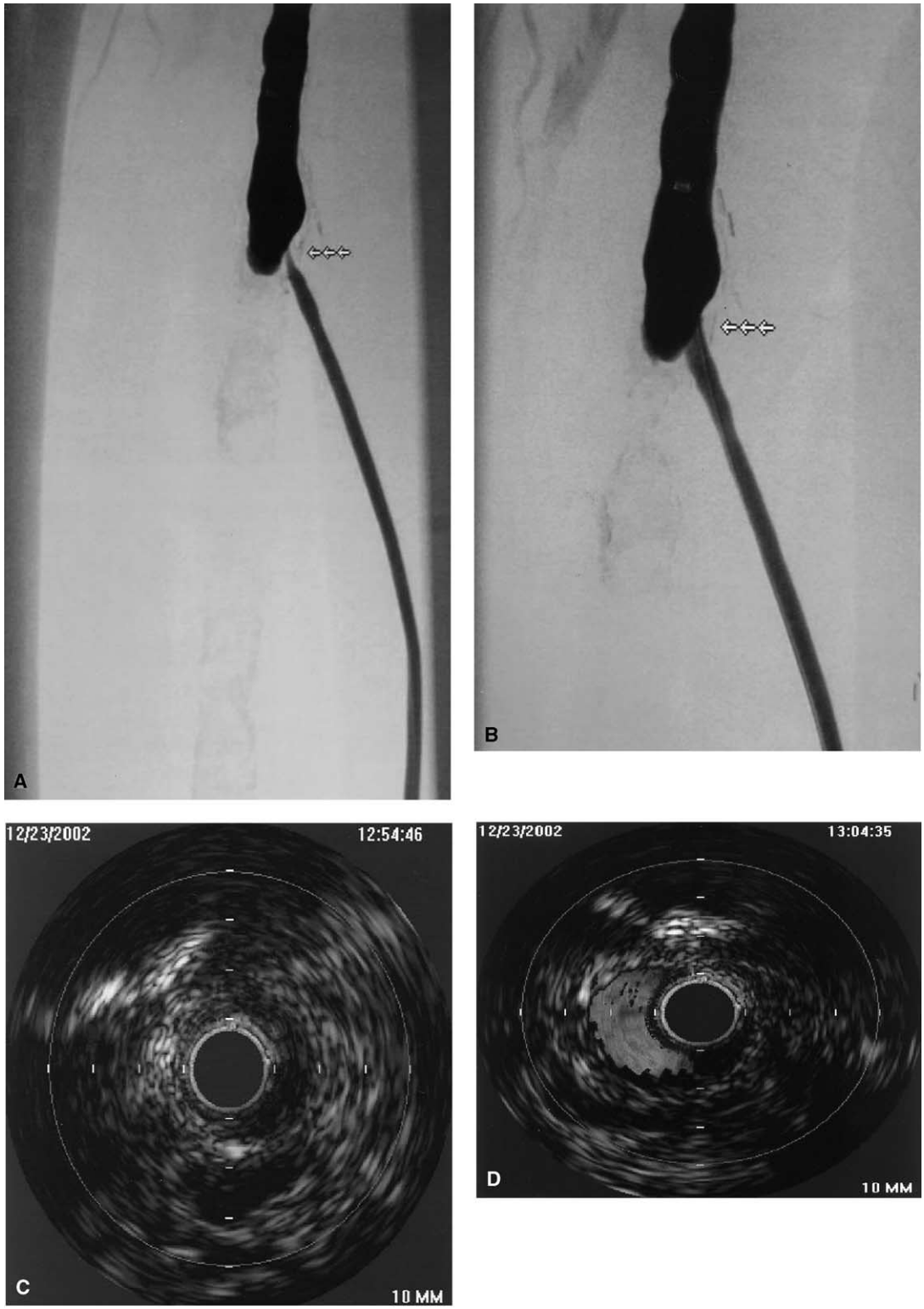

Fig 2. Pre-procedure **(A)** and post-procedure **(B)** cutting balloon angioplasty of proximal vein graft stenosis. Note highly calcified superficial femoral artery (*arrows*). Velocity at duplex scanning, 402/99 (ankle-brachial index, 0.99). Pre-procedure **(C)** and post-procedure **(D)** intravascular ultrasound images of cutting balloon angioplasty demonstrate excellent luminal restoration. However, the patient continued to have elevated flow at duplex scanning (374/87; ankle-brachial index, 0.98).

One patient with a proximal stenosis at the location of the origin of the saphenous vein graft from the superficial femoral artery had persistent elevation in velocity at duplex scanning at the 1-month visit. This patient had a highly calcified superficial femoral artery, and despite the excellent angiographic and intravascular ultrasound images (Fig 2, *A-D*) at cutting balloon angioplasty, did not demonstrate a significant decrease in velocity at the 1-month duplex scanning examination. The patient opted for an open surgical revision during the follow-up clinical visit. Because of the extensive amount of calcification seen in the inflow vessel (superficial femoral artery), a jump graft was performed from the common femoral artery to the proximal portion of the saphenous vein bypass graft. A repeat angiogram was not obtained before revision; hence the specific cause for failure could not be established with certainty. During a mean follow-up of 11.4 ± 7 months, no other recurrence was observed, and there was no graft occlusion. Velocity at duplex scanning in all other patients during follow-up showed no significant change; all 19 patients underwent duplex scanning at 3 months.

Patient demographic data

	Above-knee (n = 10)	*Below-knee (n = 9)*
Male patients	7	4
Mean age (y)	66 ± 10	67 ± 11
Diabetes	3	4
Coronary artery disease	4	4
Hypertension	6	5
Smoking	6	3
Pre-duplex velocity	364 ± 62	382 ± 53
Post-duplex velocity	136 ± 39	153 ± 61†

*Given in cm/s at 1-month follow-up.
†One patient with persistent elevated velocity at 1-month visit is not included.

DISCUSSION

The major limiting factor for long-term patency of vein bypass grafts is recurrent stenosis. The short-term risk for graft occlusion in the presence of an unrevised critical stenosis is nearly 80%.[11] The method of choice (open surgery vs PTA) for treatment of the culprit lesions continues to remain controversial. Perler et al[12] reported an experience consisting of 24 instances of PTA in 37 individual vein graft stenoses in 19 grafts. This series excluded all those grafts that required initial thrombolysis. Recurrent lesions occurred in 67% of grafts. The 3-year primary patency rate was 22%, and repeat PTA provided little additional benefit, so the secondary patency rate remained limited to 27%. Similarly, Sheridan et al[13] detected 22 vein graft stenoses in a group of 175 monitored grafts. Intervention with PTA or surgical revision was initially successful in all lesions. Within 6 months, however, 15 of 16 stenoses managed with angioplasty recurred, whereas 5 of the 6 surgical revisions remained patent. Bandyk et al[14] reported their results with secondary intervention for infrainguinal vein graft failure, and demonstrated that long-term durability was clearly superior with surgical revision, especially if the stenotic segment was completely excised and replaced with a short interposition vein graft. Whittemore et al[15] used PTA in 30 patients with 54 stenotic lesions in autogenous vein grafts after infrainguinal reconstruction. The 5-year primary patency rate was 18%, with no significant differences observed among patency rates on the basis of initial indication, length of stenotic lesion, or requirement for preliminary thrombolytic therapy. They demonstrated that the 3-year patency rate associated with vein graft lesions requiring only a single angioplasty procedure were significantly higher (59%) than those requiring repetitive dilation (6%). However, when PTA was used selectively, the outcome was similar to that with open surgical repair (63% vs 63% at 2 years).[16] Of interest, fewer graft failures occurred in the PTA group compared with the open surgical group, although the repeat intervention rate for PTA was higher. In another report of single lesions less than 1.5 cm long with grafts more than 3.0 mm in diameter PTA yielded reasonable results.[17] In the authors' experience, use of standard balloons to treat peripheral vein grafts resulted in about a 20% incidence of requirement for bail-out stenting, with a primary patency rate of about 40% at 1 year. However, the final role of PTA versus open surgical revision continues to remain a topic of controversy, and no consensus is currently available.

When operations are performed to treat recurrent stenosis, the lesions typically are pale, firm, and rubbery at gross inspection. The cellular component of these neointimal lesions is thought to be primarily smooth muscle cells that have proliferated and migrated from the media.[18] The fibrous nature of these lesions may make them less responsive to PTA, as opposed to de novo atherosclerotic lesions. Significantly higher pressure may be required to dilate these fibrous lesions, often resulting in areas of extensive dissection or rupture from the hoop stress being reflected to the adjacent nonstenotic region. This may be overcome by controlled and localized areas of microincisions with the cutting balloon, sparing the interincisional segments. Animal experiments have demonstrated that cutting balloons can minimize the vessel wall response to injury, which may be ultimately responsible for the series of cellular and subcellular events leading to myointimal hyperplasia and recurrent stenosis.[19,20] Coronary data have been controversial with the use of the cutting balloon. However, in many of the coronary studies, the cutting balloon was used primarily to treat de novo atherosclerotic lesions. In a recent study involving 1238 lesions, the use of the cutting balloon did not reduce the rate of recurrent stenosis, compared with conventional balloon PTA.[21] These authors concluded that cutting balloons should be reserved for resistant lesions and in-stent recurrent stenotic lesions.[21] This was further demonstrated by studies involving the use of cutting balloons for treatment of neointimal hyperplasia.[22,23]

Our study was based on this concept of using cutting balloon technology to treat focal vein grafts with a diameter

greater than 3 mm. Engelke et al[24] evaluated the use of cutting balloon PTA to treat peripheral vein graft stenosis in 15 patients. No local patient-related complications were reported, and at a mean follow-up of 10 months only two recurrent stenoses were observed. We were able to achieve similar results with focal lesions in optimal diameter conduits. In our report the single recurrence was seen in a lesion with extensive inflow vessel calcification. Despite the shortcomings of a small sample size in our observational study, the results are superior to published data on conventional PTA to treat vein graft stenosis, and compare favorably with open surgical revision.

In conclusion, cutting balloon PTA is a useful endovascular tool in patients with recurrent stenosis. Further prospective randomized trails are required to establish its role in the routine treatment of neointimal lesions.

REFERENCES

1. Belkin M, Knox J, Donaldson MC, Mannick JA, Whittemore A. Infrainguinal arterial reconstruction with nonreversed greater saphenous vein. J Vasc Surg 1996;24:957-62.
2. Taylor LM Jr, Edwards JM, Porter JM. Present status of reversed vein bypass grafting: five-year results of modern series. J Vasc Surg 1990;11: 193-206.
3. Wixon CL, Mills JL, Westerband A, Hughes JD, Ihnat DM. An economic appraisal of lower extremity bypass graft maintenance. J Vasc Surg 2000;32:1-12.
4. Szilagyi DE, Elliott JP, Hageman JH, Smith RF, Dall'olmo CA. Biological fate of autogenous vein implants as arterial substitutes: clinical, angiographic, and histopathologic observations in femoro-popliteal operations for atherosclerosis. Ann Surg 1973;178:232-46.
5. Mills JL, Bandyk DF, Gahtan V, Esses GE. The origin of infrainguinal vein graft stenosis: a prospective study based on duplex surveillance. J Vasc Surg 1995;21:16-22.
6. Bandyk DF, Schmitt DD, Seabrook GR, Adams MB, Towne JB. Monitoring functional patency of in situ saphenous vein bypasses: the impact of a surveillance protocol and elective revision. J Vasc Surg 1989;9:286-96.
7. Erickson CA, Towne JB, Seabrook GR, Freischlag JA, Cambria RA. Ongoing surveillance of vascular laboratory surveillance is essential to maximize long term in situ saphenous vein bypass patency. J Vasc Surg 1996;23:18-27.
8. Mills JL, Fujitani RM, Taylor SM. The characteristics and anatomic distribution of lesions that cause reversed vein graft failure: a five-year prospective study. J Vasc Surg 1993;17:195-204.
9. O'Mara CS, Flynn WR, Johnson ND, Bergan JJ, Yao JS. Recognition and surgical management of patent but hemodynamically failed arterial grafts. Ann Surg 1981;193:467-76.
10. Idu MM, Buth J, Cuypers PH, Hop WC, van de Pavoordt ED, Tordoir JM. Economizing vein graft surveillance programs. Eur J Vasc Endovasc Surg 1998;15:432-8.
11. Mills JL Sr, Wixon CL, James DC, Devine J, Westerband A, Hughes JD. The natural history of intermediate and critical vein graft stenosis: recommendations for continued surveillance or repair. J Vasc Surg 2001;33:273-8.
12. Perler BA, Osterman FA, Mitchell SE, Burdick JF, Williams GM. Balloon dilation versus surgical revision of infrainguinal autogenous vein graft stenoses: long-term follow-up. J Cardiovasc Surg 1990;31: 656-61.
13. Sheridan J, Thompson J, Gazzard S. The role of transluminal angioplasty in the management of femoro-distal graft stenosis. Br J Radiol 1989;62(suppl):S564.
14. Bandyk DF, Bergamini TM, Towne JB, Schmitt DD, Seabrook GR. Durability of vein graft revision: the outcome of secondary procedures. J Vasc Surg 1991;13:200-10.
15. Whittemore AD, Donaldson MC, Polak JF, Mannick JA. Limitations of balloon angioplasty for vein graft stenosis. J Vasc Surg 1991;14:340-5.
16. Avino AJ, Bandyk DF, Gonsalves AJ, Johnson BL, Black TJ, Zwiebel BR, et al. Surgical and endovascular intervention for infrainguinal vein graft stenosis. J Vasc Surg 1999;29:60-71.
17. Sanchez LA, Suggs WD, Marin ML, Panetta TF, Wengerter KR, Veith FJ. Is percutaneous balloon angioplasty appropriate in the treatment of graft and anastomotic lesions responsible for failing vein bypasses? Am J Surg 1994;168:97-101.
18. Chervu A, Moore WS. An overview of intimal hyperplasia. Surg Gynecol Obstet 1990;171:433-47.
19. Lary B. Coronary artery incision and dilatation. Arch Surg 1980;115: 1478-80.
20. Barath P. Microsurgical dilation concept: animal data. J Invas Cardiol 1996;8:2-5A.
21. Mauri L, Bonan R, Weiner B, Legrand V, Bassand JP, Popma J, et al. Cutting balloon angioplasty for the prevention of restenosis: results of the cutting balloon global randomized trial. Am J Cardiol 2002;15: 1079-83.
22. Adamian M, Marsico F, Di Mario C. Cutting balloon for the treatment of in-stent restenosis: a matched comparison with conventional angioplasty and atherectomy. Circulation 1999;100:I-305.
23. Di Mario C, Marisco F, Admian M, Karvouni E, Albiero R, Colombo A. New recipes for instent restenosis: cut, grate, roast or sandwich the neointima? Heart 2000;84:471-5.
24. Engelke C, Morgan RA, Belli AM. Cutting balloon percutaneous transluminal angioplasty for salvage of lower limb arterial bypass grafts: feasibility. Radiology 2002;223:106-14.

Submitted Sep 14, 2003; accepted Oct 14, 2003.

DISCUSSION

Dr Douglas Hood (Los Angeles, Calif). Drs Kasirajan and Schneider present a retrospective study of 19 focal vein graft stenoses treated with cutting balloon angioplasty with excellent results, with restenosis at the treated site occurring in only one patient with a mean follow-up of 11.4 ± 7 months. They tell us that all vein stenoses of a ≤2 cm in length seen by the two authors during the study period were treated with this technique, presumably eliminating selection bias for the study. Data from the study was prospectively collected. However, no control group of patients who had undergone alternative treatment methods such as plain old balloon angioplasty or surgical graft revision was included for comparison. Thus, no definitive conclusions regarding the role of this technique in the treatment of vein graft stenosis can be made. This report tells us that cutting balloon angioplasty can be performed, but does not tell us that it should be performed.

There are, of course, a number of potential attractive features of the endovascular management of vein graft stenosis. Not the least of these is the avoidance of a surgical incision in a reoperative field, which has a higher risk of infection and failure of primary wound healing, and avoidance of the need to identify a suitable segment of autogenous vein for use as a patch or interposition graft.

Our experience with endovascular management of vein graft stenosis due to intimal hyperplasia has been less than optimal, as demonstrated in a report recently published in the *Archives of Surgery* by Steve Katz, a member of our group. The failure rate at

6 months in that series was 35%, with 54% failure at 12 months. For this reason, balloon angioplasty has not been a preferred technique for the management of this problem, and we have relied on open surgical methods of correction.

Cutting balloons are approved and marketed for use in the coronary arteries, but of course may have additional uses in the peripheral circulation. I have seen a few case reports of the successful use of these balloons for dialysis access stenosis, the pathology of which (intimal hyperplasia occurring within a segment of vein) is similar to the vein graft stenoses described in this report. This is the first report I have seen of the use of cutting balloons for the treatment of peripheral venous bypass graft stenosis.

I have both technical and methodological questions for the authors. First, it is frequently recommended in the literature concerning dialysis access stenosis that prolonged balloon inflation times be used in an effort to overcome the elastic recoil of these fibrous lesions. What is your standard inflation time and your standard inflation pressures in the treatment of these cases?

During insertion, the blades on a fresh balloon are well protected within the folds of the balloon as you described, but the blades may remain exposed after balloon deflation. Is this of clinical concern? Is there any potential for vessel injury by the blades during balloon removal and are there any special techniques that we need to know to rewrap this balloon and recover those blades?

It is interesting that approximately one-half of stenoses in this report were anastomotic. Do you have any concerns about dilating anastomotic strictures and, in particular, would you recommend waiting a specific minimum amount of time before using a cutting balloon on an anastomosis?

Regarding follow-up, were these data subjected to life table analysis with estimation of standard errors? Mean follow-up in the study was 11 months, but what was the median? Is the longevity of follow-up misrepresented by a few patients with prolonged follow-up and only a few months' follow-up in the majority?

And lastly, do you envision any other specific role for this technology in the management of peripheral vascular disease?

I congratulate the authors on a well-reported series and their efforts to assess the role of endovascular technology in the management of vein graft stenosis, and would like to thank the society for the privilege of examining this work. Thank you.

Dr Karthikeshwar Kasirajan. Thank you for your kind comments and for agreeing to review the paper at the last minute, due to a change in the discussant, and getting the discussion back to me the next day.

As far as inflation time, we did not pick out a certain inflation time and compare this with conventional balloon angioplasties. I think we overcame the need to have prolonged inflation times and high pressures by producing microincisions with the cutting balloon that helped overcome hoop stress early. However, we used the cutting balloon technology's early recommendation to inflate the balloon very slowly, because you want the blades to come out perpendicular, and if you rapidly inflate the balloon, the blades may deflect to one side, so it takes about two minutes for the balloon to reach its maximum diameter. Hence, our average inflation time should have been about two minutes. We did not record the average inflation time, but I would wait for about two minutes for the balloon to reach its profile and then I would deflate it and redo it again—so probably four minutes, which is more time than a conventional balloon angioplasty. I am aware that Boston Scientific has recently removed the recommendation for slow inflation; this may be based on recent coronary data. I do not believe an inflation time of two minutes would adversely affect a peripheral saphenous vein graft.

Regarding rewrapping the balloon. If you look at the cross-sectional pictures, the blades are actually folded within the balloon before inflation. I am not sure what position the blades reach on subsequent deflation, but this did not seem to affect our ability to withdraw the balloon. There are a few case reports on coronary cases in which the blades did get stuck in the target lesion, requiring an open surgical procedure. The blades are simply glued on to the balloon surface; subsequent improvements in manufacturing techniques seem to have eliminated that problem.

Regarding concerns about lesions at the anastomosis, the majority of the proximal lesions that we treated were at the anastomosis but beyond nine months. We were a little concerned that we might cut the suture line, but we didn't have any problems in the nine patients. I don't think it is going to be a problem, if we avoid early lesions. Probably I won't treat the proximal lesions if I see them within a month or two after the bypass. We may risk cutting the suture at that point. If we cut the suture, we can simply reinflate the balloon and open, and fix it with a patch angioplasty, but, fortunately, we have treated most proximal lesions with no suture line dehiscence.

Our median time for following these patients was 9 months, so it was a little shorter than our 11-month mean follow-up. We did not do a life table analysis because we have a total of 19 patients and only 1 immediate failure. I thought it would make more sense if we just looked at actual follow-up times.

Regarding other peripheral applications for the cutting balloons, a few of us are collecting data on the infrapopliteal vessels that we have treated with the cutting balloon, with an idea of avoiding a need for stents. A dissection in the infrapopliteal vessel using a conventional balloon angioplasty and a bail-out stent has a very poor patency. Unfortunately, the balloon is only about 1 mm in length and most infrapopliteal lesions are quite long, so we have to move multiple times to be able to hit all the target lesions. Another problem with infrapopliteal vessels is how to follow these patients once you do your angioplasty. This may mandate repeat angiograms for precise follow-up on target lesion data.

There is a peripheral cutting balloon that is going through clinical trials. It is being evaluated for dialysis vein graft stenosis. I think the balloons go up to 8 mm in diameter and should be available probably within 6 to 9 months. I think in the future, if we can demonstrate that cutting balloons decrease the need for routine stenting even in places like iliacs or renals, these balloons will certainly have a major role to play. Once peripheral cutting balloons are available, I will probably use cutting balloons primarily for all peripheral angioplasties and stent only when required. I currently primarily stent most peripheral lesions. Recent coronary data from "Rescue III" demonstrated a six-month angiographic restenosis rate of 19% for conventional balloons compared with 11% for cutting balloon PTA. Cutting balloons will certainly have a major role to play in the future.

I thank the Society for the opportunity to present our data.

Dr Ronald Dalman (Palo Alto, Calif). I think as Kasi mentioned, Doug deserves some credit for graciously agreeing to review this manuscript about a week in advance of the meeting because we had to make some changes, so we appreciate that very much, Dr Hood.

I have some questions about the technical aspects of these procedures. The intravascular ultrasound (IVUS) that you showed, does that specifically guide your treatment in some way? Do you change the position of the balloon using the IVUS? Do you use it for evidence of completion in terms of treatment? I am a little unclear on that. You showed the example where the IVUS was occlusive so presumably you heparinize these patients prior to treatment or during treatment. How much heparin do you use or for what period of time? And I guess you already discussed this a little bit, but are you using the cutting balloons now primarily for tibial angioplasty? What exactly is your experience with that beyond just the anecdotes?

Dr Kasirajan. I use IVUS on all my angioplasty patients because an angiogram is a two-dimensional image and may not demonstrate exactly what is happening in the other dimensions. If I do see a significant dissection or recoil or poor stent opposition, I re-treat these lesions. Especially in post-stent placement, wall opposition is best evaluated with an IVUS. However, we didn't make any changes in the cutting balloon patients on the basis of our IVUS images. I used IVUS in this study to evaluate the difference between a conventional angioplasty and a cutting bal-

loon angioplasty, and in the case I showed in the slides, the actual microincisions made by the microtomes can be seen on the IVUS images.

As far as heparin, I heparinize all patients when I do infrainguinal angioplasty—I give them all 5000 units of heparin. I don't check activated clotting times. I don't base the heparin dose on the patient's weight. In infrainguinal angioplasty, I also give them an intra-arterial bolus of ReoPro. However, we didn't use ReoPro on any of these study patients to avoid a treatment bias. I do use ReoPro on most other infrainguinal interventions; I give them a 0.25 mg/kg body weight intra-arterial bolus of ReoPro. I don't continue them on a drip of ReoPro and additionally use aspirin and recently Plavix for most peripheral interventions. The study patients were maintained on aspirin only.

As far as tibial percutaneous angioplasty, we have quite a few patients. However, I don't have good follow-up data on them because our duplex lab doesn't image infrapopliteal vessels very well and I have not asked the patients to come back for regular angiographic follow-up exams. Ankle brachial indexes in most of these patients do not demonstrate a dramatic change, but we have had quite a number of successful limb salvages. Now I don't know what exactly we can gather from that, but at least our angiographic results look pretty good. I am sure most cardiologists would agree that a good angiographic result in the periphery is considered long-term follow-up data!

Dr Sheila Coogan (Palo Alto, Calif). Kasi, I enjoyed your presentation, and I think that because of the fibrous nature of vein graft stenosis I agree with the cutting balloons. I started using them myself, but one thing is curious. In the coronary system, I haven't actually kept the balloon inflated for 2 to 4 minutes and since much of this is what is done in the coronary system, it is surprising that in the coronaries the patients would tolerate a balloon inflation of 2 to 4 minutes. Is that standard practice in the coronary circulation?

Dr Kasirajan. I'm not sure about the actual occlusion time. By that, I mean you don't leave it inflated for 2 minutes. When you use a cutting balloon, the initial recommendation was to take it up really slowly, so it does take about a 2-minute inflation time, not occlusion time.

Dr Coogan. I'm just surprised the cardiologists wouldn't find they had ischemia that was problematic with a 2- to 4-minute balloon inflation.

Dr Kasirajan. They probably go up faster and come down as you have suggested. You know they are always monitoring these patients very closely so if there are electrocardiogram changes or angina, they would bring the balloons down immediately. I'll let you know what I find when I start doing my drive-by coronary interventions!

Dr George Andros (North Hollywood, Calif). Most of us have been around long enough to see endovascular therapies come and go. On the one hand you want to accept them, and on the other hand you see them go as well. I would just urge a little respectful waiting until we have the answer on this.

The question I have is, would you just tell us the difference between your outcomes on midbody stenoses and anastomotic stenoses, both proximal and distal, since it depends if it is proximal or distal and whether you reverse the vein or not?

Dr Kasirajan. Fortunately we had only one failure and that was a proximal lesion, so there was really no difference between a proximal anastomotic, midbody, or distal anastomotic lesion. There was a single failure so I can't give you any statistical data on that. There was no difference between reversed and in situ vein bypasses. We are still continuing to follow these patients. We hope to have 2-year data in about 30 to 40 patients, which may make more sense, and also are thinking of comparing it with conventional balloon angioplasty for which we already have plenty of data. The one nice thing is that, if you look at all the published data on conventional balloon angioplasty, cutting balloon certainly has done way better. We limited ourselves to focal lesions in veins that were at least 3.5 mm in diameter, so there may be a selection bias, but cutting balloon angioplasty compares very favorably to open surgery and it is much better than a conventional balloon angioplasty.

Dr Sam Ahn (Los Angeles, Calif). One question and comment. George Andros actually is the one who told me this, but on these vein graft restenoses, you have to inflate them for a long time and at very high pressures to get efficacy, and so sometimes I'll have to take them out to 16 atmospheres and sometimes even 8 atmospheres of pressure, and it requires multiple inflations, 2, 3, 4 times for 30 seconds each and that's a total of about 2 to 3 minutes' total inflation time. That is comparable to what you have done, and so far, knock on wood, I have not had to put a stent in any of these vein graft restenoses. This is anecdotal, but I think that until you do a prospective randomized trial it is very hard to interpret the results of your data.

The question I have for you, which is completely unrelated, is this: Is the shaft size or the introducer sheath requirement larger with these cutting balloons because of the extra space that these blades take up, and if so is there an increased risk of access bleeding complications?

Dr Kasirajan. No, the balloons require a standard 5 French sheath. I'm not sure whether it will go through a 4 French. I always use an up-and-over sheath and I always use an up-and-over 6 French Pinnacle Destination sheath. I take them all through a 6 French in case I need to place a bail-out stent.

I totally agree with you—this is our conclusion in the manuscript. Until we have a large prospective randomized trial, we can't come to a valid conclusion. These are preliminary data—a feasibility study. The use of cutting balloons my help avoid the prolonged inflation times and high pressure needed for conventional balloon angioplasty. You produce your initial microincisions, and hence you don't need a high pressure to be able to get the lesion to fracture when using the cutting balloon. Additionally, producing your fracture along the predetermined microincisions produced by the microtomes eliminates the risk of an uncontrolled dissection. That is what we are hoping to achieve and have, in our limited series, by using the cutting balloon.